

### REMARKS

The issues outstanding in the Office Action mailed October 25, 2000, are the requirement for Election/Restriction and the rejections under 35 U.S.C. §112, §102, §103 and the doctrine of obviousness-type double patenting. It is noted that claims 13-15 and 21 have been indicated as being allowed. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

At the outset, it is noted that at page 4, the Office Action requests clarification concerning text on page "1A" of the specification. It is not understood what page the Examiner is referring to, inasmuch as the specification which was filed September 2, 1997, contains no page 1A. However, it is believed that, perhaps, the Examiner is confusing the specification as originally filed with the text of the application as amended under Article 34 of the PCT. However, applicants' requested via a paper filed September 2, 1997 (with the application) that examination in the U.S. national phase be based on the original PCT application as filed. Thus, it is not seen that page 1A is before the Examiner for consideration. Should the Examiner wish any further clarification, please advise,

#### Election/Restriction

Applicants traverse of the Election/Restriction requirement is maintained. It is again noted that the present case is a PCT National Phase application, and thus subject to the unity of invention requirements codified in 37 C.F.R. §1.475. Under this section of the rules, it is submitted that the groups of claims herein should be maintained together as the same procedure and same special patentable feature are applied regardless of how the detection techniques are employed in the various groups of claims. The inventive concept, for example, as set forth in claim 1, relates to the use of magnetically-coupled structure specific substances to measure analytes in a liquid or solid phase. Selection of particular bound magnetic markers is wholly conventional in view of the guidance given in the specification, and does not require undue experimentation. The inventive concept does not vary with the particular material or analyte bound, but all bound ligands are used in the invention in a similar manner. Thus, the inventive concept does not change regardless of any material employed therein. The materials are, in fact, especially adapted for use in the process claimed, and thus are part of a single inventive concept. While the Office Action, at page 2, disputes this argument by doubting patentability

of the claims based on this special technical feature, it is submitted that this reflects a misunderstanding of the PCT unity of invention rules, in which patentability is not a prerequisite for unity of invention. The fact that the claims all recite the same special technical feature is sufficient to maintain the groups of claims together.

Moreover, the Office Action does not respond to the arguments concerning the impropriety of the election of species, at pages 1 and 2 of the Response filed April 24, 2000. Without burdening the record by repeating this discussion, it is maintained that the election of species has inherently been reformulated by the examiner's acceptance of applicants' election of "magnetite-labeled anticollagen," and SQUID, in other words, species of each of the magnetic material, structure-specific substance and field sensor. In any event, however, withdrawal of the election/restriction requirement is respectfully requested.

#### **Rejections Under 35 U.S.C. §112**

Claims 1, 2, 4, 5, 8-25 and 39 have been rejected under 35 U.S.C. §112, second paragraph. Reconsideration of this rejection is respectfully requested. Grammatical and typographical changes have been made to the claims, in order to respond to the discussion at pages 5 and 6 of the Office Action. Thus, it is submitted that the claims fully satisfy the requirements of the statute and withdrawal of this rejection is respectfully requested. Moreover, it is submitted that the claims fully satisfied the requirements of §112 even prior to the above amendments, and that the amendments have been made merely as in a clarifying nature.

#### **Rejections Under 35 U.S.C. §102**

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. §102(b) over JP '442 (TDK). Reconsideration of this rejection is respectfully requested. TDK teaches a method of determining the concentration of antigen or antibody in a liquid sample, known in the art agglutination assays, as noted page 7 of the Office Action. It is not seen that this disclosure, however, anticipates or suggests a method determining limited magnetic flux density of non-glutinated matter, i.e., in a heterogenous assay. Withdrawal of the rejection is therefore respectfully requested.

Claims 19 and 22 -24 have been rejected under 35 U.S.C. §102(b) over Cohen *et al.* (EP '384). Reconsideration of this rejection is also respectfully requested. Cohen is also not seen to disclose or suggest a heterogenous assay technique. Withdrawal of this rejection is therefore also respectfully requested.

Claims 1, 2, 4, 5, 8, 11, 12 and 18 have been rejected under 35 U.S.C. §102(b) over Josephson *et al.* '297. Reconsideration of this rejection is also respectfully requested. Josephson describes a ligand binding assay based on measurement of relaxation rates of a solvent obtained by a magnetic resonance spectrometer. It is not seen that this method, in which proton relaxation rates produced by magnetic material (i.e., the relaxation rate of proton spin in the nucleus of the atom) are measured suggests determination of magnetic remnance in an immunoassay. Moreover, it should be noted that patentees measure relaxation rates of protons of a solvent, and not of the magnetic material itself. The present method, however, does not measure relaxation of proton spin, but relaxation of magnetization in ferromagnetic or ferrimagnetic material, which is known to involve the spin of the electrons in the outer shell of the ion atoms following the external magnetic field. Thus, the present technique does not measure proton spin in atom nuclei. Accordingly, patentees' disclosure in no way suggests the presently claimed process, and withdrawal of this rejection is also respectfully requested.

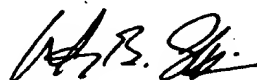
#### **Rejections Under 35 U.S.C. §103**

Claims 16-18 have been rejected under 35 U.S.C. §103 over JP '442 (TDK) taken with Cohen *et al.* Reconsideration of this rejection is respectfully requested.

Both of these references have been discussed above. As noted, these references fail to suggest heterogenous assays, and, thus, fail to suggest the presently claimed processes. Reconsideration of this rejection is therefore respectfully requested.

The claims of the application are submitted to be in condition for allowance. However, should the Examiner have any questions or comments, he or she is cordially invited to telephone the undersigned at the number below.

Respectfully submitted,



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Harry B. Shubin (Reg. No. 32,004)  
Attorney for Applicants

**MILLEN, WHITE, ZELANO & BRANIGAN, P.C.**  
Arlington Courthouse Plaza I  
2200 Clarendon Boulevard, Suite 1400  
Arlington, Virginia 22201  
Direct Dial: 703-812-5306  
Internet Address: shubin@mwzb.com

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